

An Introduction to University/Start-up Licensing

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Bayh-Dole and Technology Transfer

- Bayh-Dole (1980)
 - 35 USC 200-211, 37 CFR Chap. IV
- Universities/Non-profits/Small Business can elect title to inventions “conceived or first actually reduced to practice” under federal funding.
- Government gets license:
 - nonexclusive, irrevocable, paid-up, worldwide
 - march-in rights (almost never invoked)
- **Bayh-Dole Act strongly encourages university licensing with industry partners.**

University Obligations

- **No Assignment of patents**
except:
 - with permission of Federal Agency**or to:**
 - A patent management co. (e.g., RCT)
- Share royalties with inventors
- Remaining money to be reinvested in research
- Ensure the diligent development of the invention for the public benefit
- Preference for small businesses
- Preference for US industry

What's Different about Universities?

- Motivation
- Attitude
- Legal Framework
- Public Policy Concerns (“9 Points”)
- Sophistication/Experience
- University-Specific Policies

University – Industry Culture Clash

- Publication vs. Secrecy
- Open vs. Closed
- Conservative vs. Aggressive
- Public Benefit vs. Private Profit
- What drives the university?
 - furthering research goals
 - developing research into useful product
 - academic freedom
 - dissemination of information
 - intellect, drive and commitment
 - (bureaucracy)
 - Not necessarily monetary concerns

Start-Ups

- Strategies to preserve cash
 - Equity
 - May require University committee approval – slows the process
 - Anti-dilution protection?
 - “Shadow equity”
 - Milestone payment mirroring equity value
 - Issue: accounting treatment for company
- Deferral of payments (back-load the agreement)
 - High royalty rate, low fees
 - Escalating Fees

University Business Concerns

- Patent Prosecution
 - University will expect licensee to cover all patent prosecution costs
 - University keeps control over prosecution.
- Patent Enforcement
 - at UC: Licensee ordinarily given first right to sue
 - Standing issues in light of the latest cases from the Federal Circuit
 - Licensee expected to cover university's costs if university is joined involuntarily
 - at UC: university takes a certain flat percentage off the winnings, if any.
- Indemnification
 - at UC – Regents require that we get full indemnification for licenses.

Diligence Strategies

- Required by Bayh-Dole and encouraged for all university licenses – diligence in getting the research out for the public benefit
- Standard industry approach: “commercially reasonable efforts”
- Typical university approach: “diligent efforts” **AND**
- Defined milestones
 - Demonstrate a working prototype by [date]
 - First dose a patient in a Phase 1 Clinical Trial by [date]
 - Achieve a first commercial sale by [date]
- Mandatory Sublicensing (sometimes)

Grants, Representations, and Warranties

- License grants to all of “university’s rights”
 - What about third party rights?
 - Non-university inventors?
 - Academics love collaboration
- No blanket representation as to ownership of patents
 - in open academic environment, difficult to ensure absolute ownership or complete list of inventors
 - in addition, for UC, given size of system, hard to police
 - Will offer reps. “to the best knowledge” of the licensing officer and as of the Effective Date of the agreement
- No Warranties
 - Since university does not commercialize, expects all commercial risks to be borne by licensee.
 - No implied license to other university IP.

Retention of Rights Clauses

- Universities need to maintain freedom to operate in an open academic environment
 - *Madey v. Duke*, 307 F.3d 1351 (Fed. Cir. 2002)
- Reservation of Rights Clauses can be very broad:
 - University alone vs. all non-profits
 - Inclusion of right to use for other sponsored research?
 - University does not grant commercializing rights to other research sponsors

Sponsored Research

- Universities spent \$41.2B on research
- 66% was from the federal government
- only 7% was from industrially sponsored research
- no significant increase in sponsored research levels over the last several years

Source: 2004 AUTM survey. <http://www.autm.net/events/File/04AUTMSurveySum-USpublic.pdf>

IP Clauses from Sponsored Research Agreements

- Universities retain ownership
- Typically, sponsor gets internal use license
- Sponsor likely gets a nonexclusive license (or option to a nonexclusive license)
- Sponsor may get an exclusive license (or option to an exclusive license)
 - for public universities – bond issues
- What determines the breadth of rights?

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